UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re BAYCOL PRODUCTS LITIGATION, This Document Relates to: United States ex rel. Simpson, Plaintiff, v. Bayer Healthcare et al., Defendants.	MDL No. 1431 **DECLARATION OF LAURIE SIMPSON** Case No. 08-5758 (MJD/SRN)

LAURIE SIMPSON hereby declares pursuant to 28 U.S.C. § 1746:

1. I am the relator in this *qui tam* action. I submit this declaration in opposition to defendants' motion to dismiss. I am fully familiar with the facts and circumstances set forth herein.

2. Bayer launched Baycol in January 1998 (in conjunction with SmithKline Beecham). A few months later, I joined Bayer as the Senior Market Research Analyst for Baycol. Bayer's market research team was charged with providing independent insight and analysis to Product Management (the marketing team), with which it worked on a day-to-day basis. In addition to overall brand management and other responsibilities, it was Product Management's responsibility to develop, produce and provide direction for the use of promotional materials and promotional activities which was then implemented by the training department, the sales representatives, scientific affairs liasons and others.

3. I was a member of the Joint Marketing Team, which was composed of Product Management teams from both Bayer and SmithKline Beecham (or GlaxoSmithKline, depending

on the time frame), and the Baycol Project team, a cross-functional Bayer group which was used to help coordinate the efforts of the various departments working on Baycol.

4. My job included providing input into the development and refinement of marketing messages, assessing product perceptions of Baycol and its competitors, evaluating communications to physicians and the public regarding Baycol, and helping to turn clinical trial data into promotional messaging for Baycol. Furthermore, I also worked with Product Management in developing the Annual Strategic Business Plan and also participated in the Tactical Planning process for Baycol. The Tactical Plan detailed the promotional activities that were to be undertaken in support of the drug and the budget.

5. My work therefore involved exposure to and first-hand knowledge of many marketing and market-research issues including, the marketing and advertising of Baycol, as well as Bayer's communications with physicians regarding Baycol.

6. Throughout my employment, I obtained first-hand knowledge of a widespread campaign by Bayer to deceptively market and improperly promote Baycol, by virtue of which Bayer caused millions of dollars in claims to be paid by the Federal Government, and which is the basis for this *qui tam* action.

7. I gained this knowledge through day-to-day work involving Baycol, including my attendance and participation in meetings, emails and documents sent to me in my capacity as the lead market research analyst for Baycol, and market research I conducted involving thousands of physicians. For example, I attended a meeting on September 30, 1998, where Bayer CEO Dr. David Ebsworth specifically directed that Bayer should aggressively and deceptively market Baycol, and "push the legal boundaries," including by marketing it as comparable in efficacy to Lipitor. Also, on several occasions throughout my employment at Bayer, I approached Bayer

management with concerns relating to the marketing of Baycol, which I believe was deceptive and fraudulent conduct, but I was ignored. For example, I specifically advised the Vice President of Marketing that Bayer should clearly and explicitly communicate to sales representatives the full extent of the risks of starting patients on a 0.8 mg dose, but my advice was ignored and Bayer continued to downplay the risks.

8. In August 2001, Bayer withdrew Baycol from the market.

9. In April 2003, I was deposed by the plaintiffs in the Multi District Litigation ("MDL") which was largely composed of various personal injury and product liability lawsuits instituted by former Baycol patients, among others, claiming that they were harmed by Baycol. A full copy of my deposition transcript is annexed hereto as Exhibit A. Peter Sipkins, one of the very attorneys who represents Bayer in this action and on this motion, prepared me for the deposition for twelve days over more than six months. During such meetings, I specifically conveyed to Mr. Sipkins my concerns regarding Bayer's misconduct, and he is thus well aware that I had direct and independent knowledge of such misconduct. Nevertheless, Mr. Sipkins instructed me to listen carefully to the questions, only answer the questions put forth, and not to volunteer any information.

10. At the deposition, I followed Mr. Sipkin's instructions and answered the questions posed to me literally without volunteering any information. The plaintiffs' attorney, Hugh Plunkett, asked the questions inartfully and showed a lack of appreciation for my role, thus allowing me to easily follow Mr. Sipkins instructions. I also feared Bayer would retaliate if I volunteered information about its misconduct, particularly because I already faced disapproval from Bayer management for raising concerns with Baycol.

11. At the deposition, I properly testified that marketing and market research are indeed different, and that my role was market research, not marketing. I noted that marketing was responsible for creating the message (*i.e.* decision-marking authority). I also testified accurately that I was not personally responsible for communication (*i.e.* communicating) to physicians. However, I have never testified that I had no knowledge regarding Bayer's marketing and advertising practices, or communications to physicians. In fact, I had knowledge of such issues as well as of Bayer's downplaying of the contraindication to the Baycol label through my roles at Bayer and my involvement with Baycol. As is well known by Bayer and Mr. Sipkins, I certainly had knowledge of my allegations in the Amended Complaint concerning Bayer's misconduct and those issues as a result of my roles as the lead market research analyst, conducting market research, working on a day-to-day basis with Product Management, and participating on the Joint Marketing Team and the Baycol Project Team for Baycol. Indeed, I learned of Bayer's misconduct concerning these issues through, among other things, Bayer meetings I attended and which I participated in, emails and other communications and documents I received while employed at Bayer, market research studies I conducted, and conversations I had with physicians and with Bayer personnel. Examples of such informational sources are set forth in the Amended Complaint.

12. Similarly, while I properly testified that my roles did not involve creating the Baycol labels, I never testified that I had no knowledge of the label contents or of the related messaging derived from the labels. In fact, part of my role was to understand what messaging Bayer and Product Management wanted to convey about Baycol and then assess the effectiveness of those efforts. Indeed, I was directly involved with such issues, and gained knowledge of Bayer's misconduct regarding them from my roles at Bayer.

13. Any testimony I gave that Baycol was "safe and effective" was based on a definition of "safe and effective" and "proven safety" told to me by Bayer management. Specifically, in Spring 2001, I had expressed to Bayer management my concern with using such language in promoting Baycol, but was told such phrases were appropriate to describe Baycol because Baycol had been approved by the FDA. Therefore, I answered the questions at my deposition using this definition without volunteering any additional information, as I was instructed to do by Mr. Sipkins and out of fear of retaliation by Bayer. Indeed, I did have knowledge of Bayer's misconduct in *overstating* the safety and efficacy of Baycol, which, as detailed in the Amended Complaint, I learned of as a result of my roles at Bayer and my involvement with Baycol.

14. After my deposition, I continued to believe that Bayer's conduct was wrong and felt it should be disclosed. I approached Bayer's attorneys and expressed my concerns regarding Bayer's misconduct and my deposition.

15. Subsequent to the deposition, I raised concerns with Bayer Management regarding their inappropriate and fraudulent marketing of another drug. I believe that the fact that I continued to raise concerns with Bayer regarding their misconduct directly led to my termination by Bayer on January 1, 2005.

16. I first approached the Federal Government in early 2005, disclosing information upon which this action is based. Subsequently, I commenced this action in October 2006.

Dated: October 14, 2009

LAURIE SIMPSON

CERTIFICATE OF SERVICE

I, Robert Sadowski, hereby certify that on this 15th day of October, 2009, true and correct copies of the foregoing Declaration of Laurie Simpson were electronically filed and served on all attorneys of record and liaison counsel.

s/ Robert W. Sadowski
Robert Sadowski